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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/210,031

Applicant(s)

Lorincz

Examiner

John S. Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 31 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 36-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 36-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The rejection of claims 1-4 under 35 U.S.C. § 102(e) as being anticipated by Dunphy in the Office action mailed 18 April 2001 is withdrawn in view of the amendment received 31 July 2001 and because Dunphy does not explicitly show a tissue collection medium that comprises a chelating agent.

Claim Rejections - 35 USC § 103

2. The rejection of claims 5-11, 15-20, 24-27, and 33-35 under 35 U.S.C. § 103(a) as being unpatentable over Dunphy in view of Hurley in the Office action mailed 18 April 2001 is withdrawn in view of the amendment received 31 July 2001 and because the previous grounds of rejection was not based on the teaching of use of alcohol and EDTA by Dunphy.
3. The rejection of claims 13, 14, 29-30, and 32 under 35 U.S.C. § 103(a) as being unpatentable over Dunphy in view of Hurley in view of Harrison in the Office action mailed 18 April 2001 is withdrawn in view of the amendment received 31 July 2001 and because the previous grounds of rejection was not based on the teaching of use of alcohol and EDTA by Dunphy.
4. The rejection of claims 21-23, 28, and 31 under 35 U.S.C. § 103(a) as being unpatentable over Dunphy in view of Hurley in view of Harrison in view of Wainwright in the Office action mailed 18 April 2001 is withdrawn in view of the amendment received 31 July 2001 and because the previous grounds of rejection was not based on the teaching of use of alcohol and EDTA by Dunphy.

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. §102(e), (f) or (g) prior art under 35 U.S.C. §103(a).

8. Claims 36-48, 51-54, 58, 59, and 61 are rejected under 35 U.S.C. §103(a) as being unpatentable over Dunphy et al.

The claims are drawn to tissue collection medium comprising alcohol, a cross-linking agent, and a chelator, and methods of use of the medium. In some embodiments the medium is

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buffered at neutral or acidic pH levels. In some embodiments particular volumes of medium are claimed, and medium that inhibits RNA, DNA, and protein degradation is claimed.

Dunphy shows in example 4, columns 7 and 8, a medium for fixing tissue for histological procedures. The aqueous medium comprises 3.5-4% ethanedial, a cross-linking fixative, and 15-25% ethanol. Dunphy shows in column 5, lines 1-7 that a chelating agent EDTA is a useful addition because it acts as a bacteriostatic agent and because it inhibits bacterial enzymatic activity. Dunphy shows that is desirable to add a buffering agent in column 6 to buffer to pH 6.8-7.8, and further shows to use media with an acidic pH in column 3, lines 18-19 and column 4, lines 16-18. Dunphy does not explicitly show a medium for tissue collection that comprises EDTA, or is buffered to neutral or acidic pH levels.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the tissue collection medium of Dunphy in example 4 by addition of buffer and EDTA, because Dunphy shows that buffering agents may be used to adjust the pH to neutral or acidic levels for tissue fixation media as desired, and because Dunphy shows that EDTA has a bacteriostatic effect that is desirable in a tissue fixation medium. It would have been further obvious to use any of the recited volumes of medium in the claims as dictated by the size of the tissue sample. It would have been further obvious that inhibition of bacterial enzymatic activity by EDTA and cross-linking agents would inhibit enzymatic degradation of RNA, DNA, and protein.

9. Claims 49, 55-57, 60, and 68-74 are rejected under 35 U.S.C. §103(a) as being unpatentable over Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above, and further in view of Weber in view of Harrison.

The claims are drawn to tissue collection media comprising a cross-linking agent consisting of formaldehyde or glutaraldehyde, and their methods of use.

Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above does not show methods of using tissue treated in collection medium of DNA and protein analysis. Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above does not show cross-linking agents consisting of formaldehyde or glutaraldehyde.

Weber et al. shows on page 8 a tissue collection medium useful for in situ hybridization studies. Weber et al. shows that the medium may comprise a cross-linking fixative at a level of less than 10%, and suggests use of formalin (formaldehyde) as a cross-linking fixative.

Harrison shows discloses a tissue collection medium comprising glutaraldehyde as a cross-linking fixative at a level up to 1%. Harrison shows in column 4 that tissue treated in collection medium may be uses in in situ antigen assays.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use tissue samples treated with the collection medium of Dunphy for methods of DNA and antigen analysis because Weber shows that such media can be used for DNA hybridization analysis and Harrison shows that such media may be used for antigen analysis. It would have been further obvious to use a cross-linking agent consisting of formaldehyde or glutaraldehyde because Weber and Harrison respectively show that such aldehydes are useful cross-linking agents in tissue collection media that are compatible with further analysis of DNA or protein.

10. Claims 62-66 are rejected under 35 U.S.C. §103(a) as being unpatentable over Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above, and further in view of Wainwright.

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The claims are drawn to containers comprising collection medium as claimed in claims 58 or 59, a lid, and a brush.

Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above does not show a container comprising collection medium as claimed in claims 58 or 59, a lid, and a brush.

Wainwright shows a container, a lid fitting the container, and a brush for preserving a cell sample and comprising a pap unit.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the container of Wainwright with the tissue collection medium of Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above because Wainwright shows that such containers are convenient for obtaining pap samples for subsequent analysis.

11. Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 and further in view of Wainwright above, and further in view of Weber in view of Harrison.

The claims are drawn to containers comprising collection medium as claimed in claims 58 or 59 further comprising a cross-linking agent consisting of formaldehyde or glutaraldehyde, a lid, and a brush.

Weber et al. shows on page 8 a tissue collection medium useful for in situ hybridization studies. Weber et al. shows that the medium may comprise a cross-linking fixative at a level of less than 10%, and suggests use of formalin (formaldehyde) as a cross-linking fixative.

Harrison shows discloses a tissue collection medium comprising glutaraldehyde as a cross-linking fixative at a level up to 1%. Harrison shows in column 4 that tissue treated in collection medium may be uses in in situ antigen assays.

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It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the container comprising tissue collection medium of Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 and further in view of Wainwright above by use of cross-linking agents consisting of formaldehyde or glutaraldehyde because Weber and Harrison respectively show that such aldehydes are useful cross-linking agents in tissue collection media that are compatible with further analysis of DNA or protein.

12. Applicant's arguments filed 31 July 2001 have been fully considered but they are not persuasive. The applicants arguments that the medium of Dunphy is not compatible with molecular analysis of DNA, RNA, or protein is inconsistent with the teachings of Weber and Harrison that similar media can be used for in situ hybridization and antigen analysis. The applicants reference to a declaration of Dr. Lorincz cannot be considered since no such declaration has been entered into the instant specification, nor was such a declaration attached to the amendment received 31 July 2001. The applicants state that Dunphy does not show a medium comprising 1-15% cross-linking agent, however example 4 of Dunphy shows a tissue collection medium with a concentration of ethanedial of 3.5-4.0%. Absent evidence to the contrary, it is maintained that media meeting the recited component limitations of the claimed invention will meet the intended use limitation of suitability for cytological and molecular methods.

Double Patenting

13. The provisional rejection of claims 1-11, 15-19, and 29-35 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 and 16-20 of copending Application No. 09/598571 in the Office action mailed 18 April 2001 is withdrawn

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in view of the amendment received 31 July 2001 and because the copending application does not claim fixatives that are cross-linking agents.

14. The provisional rejection of claims 20-27 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-28 of copending Application No. 09/598571 is withdrawn in view of the amendment received 31 July 2001 and because the copending application does not claim fixatives that are cross-linking agents.

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR §1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 36-74 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29-41, 46-55, 60-66, 71-

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75, and 80 of copending Application No. 09/598571 in view of Weber et al. (WO 94/02645, cited in the Form PTO 1449 received 07 June 1999) in view of Harrison.

The claims are drawn to tissue collection medium comprising alcohol, a cross-linking agent, and a chelator, methods of use of the medium, and containers comprising the medium.

Claims 29-41, 46-55, 60-66, 71-75, and 80 of copending Application No. 09/598571 are drawn to tissue collection medium comprising alcohol, a fixative, and a chelator, methods of use of the medium, and containers comprising the medium.

Claims 29-41, 46-55, 60-66, 71-75, and 80 of copending Application No. 09/59857 are not drawn to fixatives that are cross-linking agents.

Weber et al. shows on page 8 a tissue collection medium useful for in situ hybridization studies. Weber et al. shows that the medium may comprise a cross-linking fixative at a level of less than 10%, and suggests use of formalin (formaldehyde) as a cross-linking fixative.

Harrison shows discloses a tissue collection medium comprising glutaraldehyde as a cross-linking fixative at a level up to 1%.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the tissue collection medium and its methods of use as claimed in claims 29-41, 46-55, 60-66, 71-75, and 80 of copending Application No. 09/598571 by use of formaldehyde or glutaraldehyde as a cross-linking agent fixative because Weber et al. and Harrison et al. show tissue collection media with cross-linking fixatives consisting of formaldehyde or glutaraldehyde, respectively.

This is a provisional obviousness-type double patenting rejection.

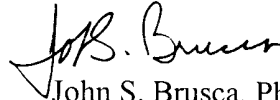
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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca, Ph.D. whose telephone number is (703) 308-4231. The examiner can normally be reached on Monday -Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-5137 for regular communications and (703) 746-5137 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


John S. Brusca, Ph.D.
Primary Examiner
Art Unit 1631

jsb
October 20, 2001